AUG 1 2001

K 003839

SUMMARY OF SAFETY AND EFFECTIVENESS

Pursuant to §513(i)(3)(A) of the Food, Drug, and cosmetic Act, Boston Scientific Corporation submits this summary of safety and effectiveness.

A. GENERAL INFORMATION

Owner Operator Submitting this Premarket Notification:	Boston Scientific Corporation One Boston Scientific Place Natick, MA 01757 (508) 652.5439
Contact Person:	Terry A. McGovern Regulatory Affairs Department
Device Generic Name:	Central Venous Catheter
Device Classification:	Unclassified

B. INDICATIONS FOR USE

The proposed catheter is intended for long-term vascular access, administration of IV fluids, blood products, medications, parenteral nutrition solutions, and blood withdrawal.

C. DESCRIPTIVE CHARACTERISTICS

The proposed device has a tapered shaft, with a smaller distal tip tapering up to a thicker walled proximal section. The shaft's proximal section has a polyester cuff. The distance between the shaft's cuff and distal tip is 50 cm; this is highlighted by printed cm markings. A hub junction connects the shaft to the catheter's proximal extension set, enabling lumen access through standard luer locks. Extension tube clamps enable closing of lumens and are color codes for lumen differentiation. Lumens are further differentiated by lumen gauge size printed on the luer locks. Catheters will include single, dual, and triple lumen configurations with an access extension for each lumen.

D. SUBSTANTIAL EQUIVALENCE

The proposed catheter is substantially equivalent to the Bard Access Systems, Inc. Hickman, Leonard and Broviac Central Venous Catheters in terms of performance and indication for use.

E. PACKAGING, STERILIZATION, AND PYROGENICITY

The proposed catheter is packaged in a heat-sealed Tyvek/mylar pouch. The product is sterilized using ethylene oxide gas.

F. CONCLUSION

Based on the information presented, Boston Scientific Corporation believes that the proposed catheter meets the minimum requirements that are considered acceptable for its intended use and is substantially equivalent to other currently marketed central venous catheters.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 2001

Ms. Theresa A. McGovern
Project Manager Regulatory Affairs
Boston Scientific Corporation
One Boston Scientific Place
Natick, Massachusetts 01760-1537

Re: K003839
Trade/Device Name: Central Venous Catheter
Regulation Number: 880.5970
Regulatory Class: II
Product Code: LJS
Dated: May 16, 2001
Received: May 17, 2001

Dear Ms. McGovern:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): New Application K003839

Device Name: Central Venous Catheter

Indications for Use:

The Central Venous Catheter is intended for long-term vascular access, administration of IV fluids, blood products, medications, parenteral nutrition solutions, and blood withdrawal.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Patricia Cucenti

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003839

Prescription Use
(Per 21 CRF 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)